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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,196	01/22/2001	Ronald J. Lebel	047711-0221	1919

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EXAMINER

DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

②

Office Action Summary	Application No. 09/768,196	Applicant(s) LEBEL ET AL.	
	Examiner Matthew F. DeSanto	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS; WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/24/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 6-9, 12-16, 18, 19, and 22-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Causey, III et al. (USPN 6,641,533).

Causey, III et al. discloses a MD electronic control circuitry, that further comprises at least one MD telemetry system, and at least one MD processor that controls, at least in part, operation of the MD telemetry system and operation of the medical device, wherein the medical device is configured to provide a treatment to a body of a patient or to monitor a selected state of the body; and b) a communication device (CD) comprising CD electronic control circuitry that further comprises at least one CD telemetry system and at least one CD processor that controls, at least in part, operation of the CD telemetry system and operation of the communication device, wherein the CD telemetry system sends messages to or receives messages from the MD telemetry system (Figures 2, 5, 7, 22, 24 and entire reference).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 6 - 10, and 12 - 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tune et al. USPN 5,630,710, and further in view of Goedeke (USPN 5,904,708) and Lyle et al. (USPN 5,956,023).

Tune et al. discloses a medical system, comprising an ambulatory medical device (MD) [Ref. # 10] comprising MD electronic control circuitry (546) that further comprises at least one MD telemetry system (562, 564, 566) and at least one MD processor (542) that controls, at least in part, operation of the MD telemetry system and operation of the medical device, wherein the medical device is configured to provide a treatment to a body of a patient or to monitor a selected state of the body; and b) a

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communication device (CD) [Ref. # 952] comprising CD electronic control circuitry that further comprises at least one CD telemetry system and at least one CD processor that controls, at least in part, operation of the CD telemetry system and operation of the communication device, wherein the CD telemetry system sends messages to or receives messages from the MD telemetry system, wherein the medical device is comprises an infusion pump (10), and wherein the CD display device is controlled to show a plurality of infusion parameters simultaneously, and wherein a first portion of the MD telemetry system is incorporated into the MD processor and a second portion of the MD telemetry system is external to the MD processor, or wherein a first portion of the CD telemetry system is incorporated into the CD processor and a second portion of the CD telemetry system is external to the CD processor, wherein (1) the MD electronic control circuitry comprises at least one external MD functional module, other than the second portion of the MD telemetry system, that is external to the MD processor, (2) the CD electronic control circuitry comprises at least one external CD functional module, other than the second portion of the CD telemetry system, that is external to the CD processor, (3) the MD processor comprises an internal MD CPU and at least one other internal MD functional module, or (4) the CD processor comprises an internal CD CPU and at least one other internal CD functional module. (Figures 2,25-30,32-41, and entire reference).

Tune et al. also discloses the communication device with a CD display controlled by at least one CD processor for providing visual feedback to the patient, and wherein the feedback comprises a display of the quantity of a consumable estimated to

be remaining in the system (512), wherein the consumable is a drug, and where the medical device wherein infusion parameters can be selected, and where the patient can program (28) there own options into the pump. (Column 3, lines 29-47), but fails to disclose wherein the telemetry device uses RF signals and the specific interactions that occur when using a cascading interface.

Goedeke discloses the use of an implantable pump with telemetry components, wherein the telemetry used is RF telemetry that is well known in the medical device art.

Lyle et al. discloses a medical fluid-processing device with a user-friendly interface that enables and disables different patient options and changes what will be displayed on the screen.

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the disclosed invention of Tune et al. with the teachings of Goedeke and Lyle et al. because it is well known to use RF telemetry with implantable medical devices or any medical devices that communicate, through telemetry, as stated in the entire reference of Goedeke (See Column 1, lines 40 to Column 2, line 6, as well as entire reference) and it is well known in the art and therefore an obvious modification to have a device with a user-friendly interface that enables and disables different patient options and changes what will be displayed on the screen so that the communication device will be more user friendly (Column 2, lines 1-11, Lyle et al.).

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tune et al. in view of Goedeke and further in view of Lyle et al. as applied to the claims above, and further in view of Er (USPN 6185461).

Tune et al. in combination with Goedeke and Lyle et al. disclosed the claimed invention except wherein the consumable is either (1) battery power remained in a replaceable CD battery in the communication device and a voltage level on the CD battery is graphically depicted with a desired resolution, or (2) battery power remaining in an MD battery in the medical device and a voltage level on the battery is graphically depicted with a desired resolution.

Er discloses a controlled system where the display, displays the battery data and battery longevity estimate graph (Figure 1 and 2 and entire reference).

At the time of the invention, it would have been obvious for a person with ordinary skill in the art to combine Tune et al. and Goedeke medical infusion device with Er replacement time indicator device and display, because according to Er, it is highly desirable to predict when a battery will failure so as to make arrangements for the replacement battery. (Column 2, lines 1-9).

5. Claims 6-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Causey, III et al. (USPN 6,641,533).

Causey, III et al. discloses the claimed invention but fails to disclose a display screen that displays the drug estimated to be remaining in a reservoir, the batter power remaining, the time-of-day indicator and finally the battery indicator.

At the time of the invention it would have been obvious to one of ordinary skill in the art to modify the disclosed invention of Causey, III et al. to include these display options because it is well known in the medical field and pump art to incorporate these options when dealing with a display on a pump and/or remote device controlling the

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pump to make the overall operating procedure by the patient or medical personnel easier. (This can be seen in the other references used in this office action [Tune et al., Goedeke, and Er and Lyle et al.])

Response to Arguments

6. Applicant's arguments with respect to claims 6-28 have been considered but are not persuasive.

7. The examiner disagrees with the interpretation of Tune et al. not teaching enabling and disabling options because Tune et al. enables and disables an alarm, and this is considered a patients parameter (claim 28), but in order to expedite the case, the examiner found a reference (Lyle et al.) that shows that level of skill in art with regards to displays and how there are several options being enabled and disabled and therefore being displayed and not being displayed. When a parameter is disabled and not displayed, this is well known in the graphic user interface, because this allows a user-friendlier interface. The reason the examiner mentioned the PDA interface was to point out the level of skill in the art of graphic user interface. One of ordinary skill in the art of programming would know to change the headings in the PDA in order to receive patient parameters. Tune and Causey III et al. both disclose displays that show patient information and allow changes or editing. The fact that Tune et al. doesn't specifically state that once an option is disabled it will no longer be displayed is an obvious occurrence in the graphic display art. The examiner is trying to show that it is well known in the graphic interface display art to have options as claimed and the capabilities to perform these options, and thus it would be obvious to use the display of

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a communication device with medical devices since they use the same displaying technology as well as PDA technology.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto
Art Unit 3763
September 19, 2005



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